

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 50-R-0003
CUSTOMER NUMBER: 27

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

Intervet Inc
29160 Intervet Lane Po Box 318
Millsboro, DE 19966

Telephone: (b)(2)High, (b)(7)f

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reas such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs		124	117	68	309
5. Cats		266			266
6. Guinea Pigs	69	349	1222	728	2299
7. Hamsters		401	444	482	1327
8. Rabbits	92	9	1294	747	2050
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(B)(6) (B)(7)(c)

DATE SIGNED

11/13/07

17a2

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientist.

- 1 Registration Number 50-R-0003
- 2 Number 68 of animals used in this study
- 3 Species (common name) dogs of animals used in this study
- 4 Explain the procedure producing pain and/or distress

All dogs were (b)(4) with a (b)(4) for the basis of determining (b)(4)

- 5 Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see Item 6 below)

Clinical signs, as observed following (b)(4) are the basis for comparing (b)(4) Therefore animals did not receive treatment for clinical signs. Typical clinical signs observed included (b)(4)

- 6 What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR, 113.102)

Agency _

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- 1 Registration Number 50-R-0003
- 2 Number 728 of animals used in this study
- 3 Species (common name) guinea pig of animals used in this study
- 4 Explain the procedure producing pain and/or distress

These animals were used for Codified (b)(4) testing for the product release testing of all Intervet (b)(4) containing products

Per (b)(4) the guinea pigs used for (b)(4) are (b)(4) with (b)(4) and observed for 3 days (b)(4) and all (b)(4) are recorded. The (b)(4) causes (b)(4) lesions which cause distress.

Per (b)(4) the guinea pigs used for (b)(4) are (b)(4) and observed for 3 days (b)(4) and all (b)(4) are recorded. The (b)(4) causes (b)(4) lesions which cause distress.

In both instances, per code, (b)(4) is the endpoint.

- 5 Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see Item 6 below)

(b)(4) is the end-point. Any intervention must be pre-approved by USDA/APHIS/VS/CVB as written in the filed Outline of Production or Special Outline. Currently, no intervention criteria are written into these procedures.

- 6 What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR, 113.102)

Agency USDA/APHIS/VS/CVB

(b)(4)

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- 1 Registration Number 50-R-0003
- 2 Number 267 of animals used in this study
- 3 Species (common name) hamsters of animals used in this study
- 4 Explain the procedure producing pain and/or distress

These animals were used for (b)(4) and were (b)(4) with (b)(4)

Per (b)(4) the hamsters used for passages are to be (b)(4) with (b)(4)

Per code, (b)(4) is the endpoint.

- 5 Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see Item 6 below)

(b)(4) is the end-point. (b)(4) occurs within 28/48 hours following the onset of symptoms. Due to the fact that (b)(4) is the required endpoint, there are no procedures available to limit discomfort, distress and pain during the challenge period.

- 6 What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR, 113.102)

Agency USDA/APHIS/VS/CVB

(b)(4)

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- 1 Registration Number 50-R-0003
- 2 Number 193 of animals used in this study
- 3 Species (common name) hamster of animals used in this study
- 4 Explain the procedure producing pain and/or distress

These animals were used for a (b)(4) to qualify a new reference to be used in a proprietary (b)(4) testing for the product release testing of Intervet's (b)(4)

The procedure for the work involves the hamsters receiving an injection intraperitoneally which in and of itself is not considered painful, however, the hamsters develop (b)(4) which does lead to pain and distress.

- 5 Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see Item 6 below)

(b)(4) is the endpoint. In 1992, (b)(4) studies were correlated to the hamster model (b)(4) in order to never have to qualify a new reference in (b)(4) again. The hamster model was used again in 1997 and 2002 and 2007.

- 6 What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR, 113.102)

Agency USDA/APHIS/VS/CVB 9CFR (b)(4)

b4

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- 1 Registration Number 50-R-0003
- 2 Number 22 of animals used in this study
- 3 Species (common name) hamsters of animals used in this study
- 4 Explain the procedure producing pain and/or distress

These animals were used for preparation (b)(4) which was subsequently used in (b)(4)

The procedure for the work involves the hamsters receiving an injection intraperitoneally which in and of itself is not considered painful, however, the hamsters develop (b)(4) and are clinically ill. The (b)(4) from affected hamsters are then harvested and used for (b)(4)

- 5 Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see Item 6 below)

Hamster (b)(4) is the only known way to produce and increase (b)(4) (b)(4) used for (b)(4)

- 6 What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR, 113.102)

Agency USDA/APHIS/VS/CVB

(b)(4)

(b)(4)

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1 Registration Number 50-R-0003

2 Number 747 of animals used in this study

3 Species (common name) rabbits of animals used in this study

4 Explain the procedure producing pain and/or distress

These animals were used for a proprietary (b)(4) testing for the product release testing of all Intervet (b)(4) containing products

Per our (b)(4) the rabbits are used in a (b)(4)

(b)(4) The rabbits are used for (b)(4) are (b)(4)

(b)(4) b4 and observed for 3 days

(b)(4) and all b4 are recorded. The challenge causes (b)(4) lesions which cause distress. The validity requirement for this test is (b)(4)

5 Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results (For Federally mandated testing, see Item 6 below)

(b)(4) is the end-point parameter measured with this approved (b)(4) test. Any intervention must be pre-approved by USDA/APHIS/VS/CVB as would be written in the filed Outline of Production or Special Outline. Currently, no intervention criteria are written into these procedures.

6 What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR, 113.102)

Agency USDA/APHIS/VS/CVB (b)(4) with APHIS approved procedure in (b)(4)